

PATENT
101.0044-03000

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: N/A

Filed: February 2, 2000

For: APPARATUS FOR INSERTING
SPINAL IMPLANTS (AS
AMENDED)

Art Unit: 3764

Examiner: Brown, M.



#10

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. This Information Disclosure Statement is being filed prior the events recited in Section 1.97(b).

The present application is a continuation of Serial No. 08/482,162 which is a divisional application of Serial No. 08/396,414 (the '414 application) filed February 27, 1995 on which Applicant claims priority rights under 35 U.S.C. § 120. The '414 application is a continuation-in-part of Serial No. 08/074,781, now U.S. Patent No. 5,484,437, which is a continuation-in-part of application Serial No. 07/968,240, now U.S. Patent No. 5,741,253, which is a continuation application of Serial No. 07/698,674, now abandoned, which is a divisional application of Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Copies of the listed documents were previously submitted to the Examiner in Applicant's prior '414 application. Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making the appropriate notations on the attached form.

Applicant brings to the Examiner's attention that the '247 patent is the subject of litigation in the United States District Court for the Central District of California, Western Division, Civil Action No. 95-0258RG, hereinafter referred to as Litigation 1. The claims of the '247 patent are directed to a fusion implant.

The '253 patent is the subject of litigation in the United States District Court for the Western District of Tennessee, Civil Action No. 98-2369GA(JSG), hereinafter referred to as Litigation 2. The claims of the '253 patent are generally directed to a method for preparing adjacent vertebrae to receive an implant.

In Litigations 1 and 2, the Defendants have asserted that various references are pertinent to the issue of validity of the '247 and '253 patents respectively under 35 U.S.C. §§102 and 103. Applicant notes for the Examiner on the attached Form 1449 in the column for the Examiner's initials the references identified by Defendants in Litigations 1 and/or 2 by the designation "Lit. 1" and "Lit. 2".

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material to patentability or constitute "prior art". If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant also brings to the Examiner's attention Applicant's co-pending applications 08/480,684 filed June 7, 1995; 08/484,927 filed June 7, 1995; and 08/480,461 filed June 7, 1995.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If it should be determined that for any reason either an insufficient or excessive fee has been paid, please charge any insufficiency or credit any overpayment necessary to ensure consideration of the information disclosure statement for the above-identified application to Deposit Account No. 50-1066. A copy of this paper is enclosed.

Respectfully submitted,

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FORM PTO-1449			Docket Number (Optional) 101.0044-03000		Application No.	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			Applicant Gary K. Michelson, M.D.			
(Use several sheets if necessary)			Filing Date January 27, 2000		Group Art Unit 3	
U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
Lit. 1	Re. 31,865	4/16/85	Roux			
	Re. 34,871	3/7/95	McGuire et al.			
	Des. 245,259	8/2/77	Shen			
	Des. 257,511	11/11/80	Zahn			
	Des. 260,525	9/1/81	Lassiter			
	Des. 281,814	12/17/85	Pratt et al.			
	350,420	10/5/1886	Dillon			
	1,137,585	4/27/15	Craig			
	2,065,659	12/29/36	Cullen			
	2,181,746	11/28/39	Siebrandt			
	2,243,718	5/27/41	De G. Moreira			
	2,372,622	3/27/45	Fassio			
	2,514,665	7/11/50	Myller			
	2,537,070	1/9/51	Longfellow			
	2,543,780	3/6/51	Hipps et al.			
	2,677,369	5/4/54	Knowles			
	2,774,350	12/18/56	Cleveland			
	2,789,558	4/23/57	Rush			
	2,832,343	4/29/58	Mose			
	2,842,131	7/8/58	Smith			
	2,878,809	3/24/59	Treace			
Lit. 2	3,128,768	4/14/64	Geistauts			
Lit. 1	3,298,372	1/17/67	Feinberg			
	3,426,364	2/11/69	Lumb			
Lit. 2	3,486,505	12/30/69	Morrison			
Lit. 1	3,604,487	9/14/71	Gilbert			
	3,605,123	9/20/71	Hahn			
	3,618,611	11/9/71	Urban			
	3,709,219	1/9/73	Halloran			
	3,720,959	3/20/73	Hahn			
	3,750,652	8/7/73	Sherwin			

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09/497590
06/06/00

Lit. 2	3,848,601	11/19/74	Ma et al.			
	3,855,638	12/24/74	Pilliar			
	3,867,728	2/25/75	Stubstad et al.			
	3,867,950	2/25/75	Fischell			
Lit. 2	3,875,595	4/8/75	Froning			
	3,888,260	6/10/75	Fischell			
Lit. 2	3,892,232	7/1/75	Neufeld			
Lit. 1	3,905,047	9/16/75	Long			
	3,915,151	10/28/75	Kraus			
	3,916,907	11/4/75	Peterson			
	3,918,440	11/11/75	Kraus			
	3,942,535	3/9/76	Schulman			
	3,948,262	4/6/76	Zaffaroni			
	3,952,334	4/27/76	Bokros et al.			
	3,987,499	10/26/76	Scharbach et al.			
Lit. 1	4,016,651	4/12/77	Kawahara et al.			
	4,027,392	6/7/77	Sawyer et al.			
	4,051,905	10/4/77	Kleine			
	4,059,115	11/22/77	Jumashev et al.			
	4,070,514	1/24/78	Entherly et al.			
	4,082,097	4/4/78	Mann et al.			
Lit. 1	4,086,701	5/2/78	Kawahara et al.			
Lit. 1	4,124,026	11/7/78	Berner et al.			
	4,142,517	3/6/79	Stravropoulos et al.			
	4,168,326	9/18/79	Broemer et al.			
Lit. 1	4,175,555	11/27/79	Herbert			
Lit. 1	4,177,524	12/11/79	Grell et al.			
	4,181,457	1/1/80	Holmes			
	4,197,850	4/15/80	Schulman et al.			
	4,206,516	6/10/80	Pilliar			
	4,222,128	9/16/80	Tomonaga et al.			
	4,232,679	11/11/80	Schulman			
	4,232,679 B1	5/31/88	Schulman			
	4,237,948	12/9/80	Jones et al.			
	4,258,716	3/31/81	Sutherland			
Lit. 1	4,259,072	3/31/81	Hirabayashi et al.			
Lit. 1	4,262,369	4/21/81	Roux			
	4,271,832	6/9/81	Evans et al.			
	4,289,123	9/15/81	Dunn			

Lit. 1	4,293,962	10/13/81	Fuson			
	4,309,777	1/12/82	Patil			
Lit. 1	4,328,593	5/11/82	Sutter et al.			
	4,333,469	6/8/82	Jeffcoat et al.			
	4,341,206	7/27/82	Perrett et al.			
Lit. 1	4,349,921	9/21/82	Kuntz			
Lit. 1	4,356,572	11/2/82	Guillemin et al.			
	4,401,112	8/30/83	Rezaian			
	4,405,319	9/20/83	Cosentino			
	4,414,979	11/15/83	Hirshorn et al.			
	4,423,721	1/3/84	Otte et al.			
	4,439,152	3/27/84	Small			
	4,450,834	5/29/84	Fischer			
Lit. 1	4,484,570	11/27/84	Sutter et al.			
	4,492,226	1/8/85	Belykh et al.			
	4,497,320	2/5/85	Nicholson et al.			
Lit. 1 and 2	4,501,269	2/26/85	Bagby			
	4,507,115	3/26/85	Kambara et al.			
	4,530,360	7/23/85	Duarte			
	4,535,374	8/13/85	Anderson et al.			
	4,535,485	8/20/85	Ashman et al.			
	4,542,539	9/24/85	Rowe, Jr. et al.			
Lit. 2	4,545,374	10/8/85	Jacobson			
	4,547,390	10/15/85	Ashman et al.			
	4,549,547	10/29/85	Brighton et al.			
	4,552,200	11/12/85	Sinha et al.			
	4,553,273	11/19/85	Wu			
	4,554,914	11/26/85	Kapp et al.			
	4,570,623	2/18/86	Ellison et al.			
Lit. 2	4,570,624	2/18/86	Wu			
	4,592,346	6/3/86	Jurgutis			
	4,599,086	7/8/86	Doty			
	4,600,000	7/15/86	Edwards			
	4,602,638	7/29/86	Adams			
	4,611,581	9/16/86	Steffee			
	4,619,264	10/28/86	Singh			
	4,628,921	12/16/86	Rousso			
	4,604,995	8/12/86	Stephens			
	4,608,052	8/26/86	Van Kampen et al.			

	4,634,720	1/6/87	Dorman et al.			
	4,636,217	1/13/87	Ogilvie et al.			
	4,636,526	1/13/87	Dorman et al.			
	4,645,503	2/24/87	Lin et al.			
	4,653,509	3/31/87	Oloff et al.			
Lit. 1	4,653,486	3/31/87	Coker			
	4,655,777	4/7/87	Dunn			
	4,661,536	4/28/87	Dorman et al.			
	4,664,567	5/12/87	Edwards			
	4,665,920	5/19/87	Campbell			
	4,677,883	7/7/87	Lee			
	4,677,972	7/7/87	Tornier			
	4,693,721	9/15/87	Ducheyne			
	4,696,290	9/29/87	Steffee			
	4,698,375	10/6/87	Dorman et al.			
	4,710,075	12/1/87	Davison			
Lit. 1	4,713,004	12/15/87	Linkow et al.			
	4,714,469	12/22/87	Kenna			
	4,721,103	1/26/88	Freedland			
	4,736,738	4/12/88	Lipovsek et al.			
Lit. 1	4,743,256	5/10/88	Brantigan			
Lit. 2	4,743,260	5/10/88	Burton			
	4,759,766	7/26/88	Buettner-Janz et al.			
	4,759,769	7/26/88	Hedman et al.			
	4,769,881	9/13/88	Pedigo et al.			
	4,772,286	9/20/88	Goble et al.			
	4,781,591	11/1/88	Allen			
	4,790,303	12/13/88	Steffee			
	4,805,602	2/21/89	Puno et al.			
	4,820,305	4/11/89	Harms et al.			
	4,830,000	5/16/89	Shutt			
Lit. 1 and 2	4,834,757	5/30/89	Brantigan			
Lit. 2	4,848,327	7/18/89	Perdue			
	4,851,008	7/25/89	Johnson			
Lit. 2	4,863,476	9/5/89	Shepperd			
	4,863,477	9/5/89	Monson			
	4,865,603	9/12/89	Noiles			
Lit. 1	4,877,020	10/31/89	Vich			
Lit. 1 and 2	4,878,915	11/7/89	Brantigan			

	4,903,882	2/27/90	Long			
	4,904,260	2/27/90	Ray et al.			
	4,904,261	2/27/90	Dove et al.			
	4,911,718	3/27/90	Lee et al.			
	4,913,144	4/3/90	Del Medico			
	4,936,848	6/26/90	Babgy			
	4,943,291	7/24/90	Tanguy			
	4,955,908	9/11/90	Frey et al.			
	4,955,885	9/11/90	Meyers			
	4,957,495	9/18/90	Kluger			
	4,960,420	10/2/90	Goble et al.			
	4,961,740	10/9/90	Ray et al.			
	4,968,316	11/6/90	Hergenroeder			
	4,969,888	11/13/90	Scholten et al.			
	4,987,904	1/29/91	Wilson			
	5,015,247	5/14/91	Michelson			
	5,015,255	5/14/91	Kuslich			
	5,026,373	6/25/91	Ray et al.			
	5,030,236	7/5/91	Dean			
	5,055,104	10/8/91	Ray			
	5,059,193	10/22/91	Kuslich			
	5,062,845	11/5/91	Kuslich et al.			
	5,071,437	12/10/91	Steffee			
Lit. 1	5,084,050	1/28/92	Draenert			
	5,102,414	4/7/92	Kirsch			
	5,105,819	4/12/92	Wallschlager et al.			
	5,108,422	4/28/92	Green et al.			
	5,112,336	5/12/92	Krevolin et al.			
	5,116,304	5/26/92	Cadwell			
	5,122,130	6/16/92	Keller			
	5,123,926	6/23/92	Pisharodi			
	5,171,278	12/15/92	Pisharodi			
	5,192,327	3/9/93	Brantigan			
	5,246,458	9/21/93	Graham			
	5,258,031	11/2/93	Salib et al.			
	5,263,953	11/23/93	Bagby			
	5,292,252	3/8/94	Nickerson et al.			
	5,306,309	4/26/94	Wagner et al.			
	5,314,427	5/24/94	Goble et al.			

Lit. 1	DE 3505567 A1 /	6/5/86	Germany			
	61-122859	6/10/86	Japan			No
	2 581 336 /	11/7/86	France			
	62-155846 /	7/10/87	Japan			No
	DE 36 08 163.A1 /	9/24/87	Germany			No
	0 260 044	3/16/88	Europe			
	0303241 A2	2/15/89	EPO			
	0 307 241	3/15/89	Europe			Yes
	91/06266	5/16/91	PCT			
	0499465 A1	8/19/92	EPO			
	DE 41 04 359.A1	8/20/92	Germany			No
	92/14423	9/3/92	PCT			
	93/01771	2/4/93	PCT			
	0551187 A1	7/14/93	EPO			
	0577179 A1	1/5/94	EPO			
	0 599 419 A2	6/1/94	Europe			Yes
	2 703 580 /	10/14/94	France			No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Lit. 2	Codman & Shurtleff, Inc.; Neurosurgical Catalog: USS 20556-20945 (1986)
Lit. 2	Codman Surgical Instruments Catalog: USS 20073-20555 (1979)
Lit. 2	Yashon, David; Spinal Injury; Second Edition; Appleton-Century-Crofts; pp. 245-258 (1986)
	Adams, et al.; Outline of Orthopaedics, Eleventh Edition; Trunk and Spine, p. 194
	Herkowitz, et al.; Principles of Bone Fusion; The Spine, Third Edition; Chapter 44, p. 1739
	Muschler, et al.; The Biology of Spinal Fusion; Spinal Fusion Science and Technique, Cotler and Cotler, pp. 9-13.
	Zindrick, et al.; Lumbar Spine Fusion: Different Types and Indications; The Lumbar Spine, Vol. 1, Second Edition, pp. 588-593 (1996)
	Gillingham, F.J., et al.; Automatic Patient Monitoring in the Ward; Brit. J. Surg., Vol. 53, No. 10, pp. 864-866 (October 1966)
	Maloney, A.F.J., et al.; Clinical and Pathological Observations in Fatal Head Injuries, Brit. J. Surg., Vol. 56, No. 1, pp. 23-31 (January 1969)
	Harris, P., et al.; Spinal Deformity After Spinal Cord Injury; Paraplegia, Vol. 6, No. 4, pp. 232-238 (February 1969)
	Gillingham, F.J., et al.; Head injuries; Proceedings of the 18 th World Congress of the International College of Surgeons, Rome, pp. 68-71 (May 28-31, 1972)
	Whatmore, W. J.; Sincipital Encephalomeningoceles; Brit. J. Surg., Vol. 60, No. 4, pp. 261-270 (April 1973)
	Whatmore, W. J.; Meningioma Following Trauma; Brit. J. Surg., Vol. 60, No. 6, pp. 496-498 (June 1973)
Lit. 1	Bagby, George W.; Wobbler Syndrome in Horses (the Ataxic Horse); Spokane County Medical Society Bulletin; Spring 1979
	Rathke, F.W., et al.; Surgery of the Spine; Atlas of Orthopaedic Operations, Vol. 1, p. 137, W.B. Saunders Co., Philadelphia (1979)
Lit. 1	Albrektsson, T., et al.; Osseointegrated Titanium Implants; Acta. Orthop. Scand.; Vol. 52:155-170 (1981)
Lit. 1	Raveh, J., et al.; Neue Rekonstruktionsmöglichkeiten des Unterkiefers bei knöchernen Defekten nach Tumorresektionen; Der Chirurg Vol. 53:459-467 (1982)

	Crock, H. V.; Practice of Spinal Surgery; Springer-Verlag/Wien, New York (1983)
Lit. 1 and 2	DeBowes, R.M., et al.; Study of Bovine...Steel Baskets; Transactions of the 29th Annual Meeting; Orthopaedic Research Society, Vol. 8, p. 407, March 8-10 (1983)
	O'Neill, P., et al.; Spinal Meningoceles in Association with Neurofibromatosis; Neurosurgery, Vol. 13, No. 1, pp. 82-84 (July 1983)
Lit. 2	Brandt, L., et al.; A Dowel Insert for Anterior Cervical Interbody Fusion; J. Neurosurg. 61:793-794 (October 1984)
	Whatmore, W.J., et al.; The Coventry Cervical Spreader and Dowel Insert; ACTA Neurochirurgica, Vol. 70, FASC. 1-2 (1984)
Lit. 1	Raveh, J., et al.; Use of the Titanium-coated Hollow Screw and Reconstruction Plate System in Bridging of Lower Jaw Defects; J. Oral Maxillofac Surg. 42:281-294 (1984)
Lit. 1 and 2	Otero-Vich, Jose M.; Anterior Cervical Interbody Fusion with Threaded Cylindrical Bone; J. Neurosurg 63:750-753 (November 1985)
Lit. 1	Morscher, E., et al.; Die vordere Verplattung der Halswirbelsäule mit dem Hohlschrauben-Plattensystem aus Titanium, <i>Der Chirurg</i> , Vol. 57, pp. 702-707 (1986) with English Translation
Lit. 1 and 2	Bagby, G.W.; Basket Implant Facilitates Spinal Fusion; Orthopedics Today, Vol. 7, No. 10, (October 1987)
Lit. 1	Butts, M. K., et al.; Biomechanical Analysis of a New Method for Spinal Interbody Fixation; 1987 Symposium, American Society of Mechanical Engineers, "Advances in Bioengineering", Boston, MA (Dec. 13-18, 1987)
Lit. 1	Crawley et al.; A Modified Cloward's Technique for Arthrodesis of the Normal Metacarpophalangeal Joint in the Horse; <i>Veterinary Surgery</i> , Vol. 17, No. 3, pp. 117-127 (1988)
Lit. 1-	Raveh, J., et al.; Surgical Procedures for Reconstruction of the Lower Jaw Using the Titanium-Coated Hollow-Screw Reconstruction Plate System: Bridging of Defects; <i>Otolaryngologic Clinics of North America</i> ; Vol 20, No. 3 (August 1987)
	Whatmore, W. J.; Proceedings of the Society of British Neurological Surgeons; <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> , 50:1093-1100 (1987)
Lit. 2	Goldthwaite, N., et al.; Toward Percutaneous Spine Fusion; Ch. 45; <i>Lumbar Spine Surgery</i> ; C.V. Mosby Company, pp. 512-522 (1987)
Lit. 1 and 2	Bagby, G.W.; Arthrodesis by the Distraction-Compression Method Using a Stainless Steel Implant; <i>Orthopedics</i> , Vol. II, No. 6, pp. 931-34 (June 1987)
Lit. 1	Itoman, M., et al.; Banked Bone Grafting for Bone Defect Repair--Clinical Evaluation of Bone Union and Graft Incorporation; <i>J. Jpn. Orthop. Assoc.</i> 62:461-469 (1988)
	Kane, W.J.; Direct Current Electrical Bone Growth Stimulation for Spinal Fusion; <i>Spine</i> , Vol. 13, No. 3, pp. 363-365 (March 1988)
	The SpF-T Spinal Fusion Stimulator: An Efficacious Adjunct that Meets the Diverse Needs of Spine Patients; EBI Medical Systems; (August 1991)
	Schmitz et al.; Performance of Alloplastic Materials and Design of an Artificial Disc; <i>The Artificial Disc</i> , Brock, Mayer, Weigel; pp. 23-34 (1991)
	The Use of Direct Current for Electrically Induced Osteogenesis; The Positive Effect of an Electronegative charge on Bone Growth; EBI Medical Systems (Feb. 1993)
	Mylonas, C., et al.; Anterior Cervical Decompression and Fusion Using the Coventry Cervical Spreader and Dowel Insert; <i>British Journal of Neurosurgery</i> , 7:545-549 (1993)
	Fusion of the Lumbar Spine; Anterior Monosegmental Fusion L5-S1, <i>Atlas of Spinal Operations</i> , Thieme, pp. 270-274 (1993)
	<i>Spine Basics</i> , Danek Group, Inc., Glossary (1993)
	<i>Lumbar Spine Surgery, Techniques and Complications; History of Lumbar Spine Surgery</i> (1994); pp. 11-15, 27, 30, 35-45, 265-268.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

	5,324,295	6/28/94	Shapiro			
	5,352,229	10/4/94	Goble et al.			
	5,360,430	11/1/94	Lin			
	5,364,399	11/15/94	Lowery et al.			
	5,370,662	12/6/94	Stone et al.			
	5,370,697	12/6/94	Baumgartner			
	5,393,036	2/28/95	Sheridan			
	5,396,880	3/14/95	Kagan et al.			
	5,397,364	3/14/95	Kozak et al.			
	5,425,772	6/20/95	Brantigan			
	5,435,723	7/25/95	O'Brien			
	5,489,307	2/6/96	Kuslich et al.			
	5,489,308	2/6/96	Kuslich et al.			
	5,571,109	11/5/96	Bertagnoli			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	106 101	7/21/39	Sweden			
Lit. 1	1961531	7/9/70	Germany			
	24 46 039	4/3/75	Germany			No
	2 295 729	7/23/76	France			No
	GB 2076657 A	12/9/81	Great Britain			
	DE 3101333 A1	12/24/81	Germany			
	57-29348	2/17/82	Japan			
	GB 2082754 A	3/10/82	Great Britain			
	DE 3132520 A1	6/16/82	Germany			
Lit. 2	0 077 159	4/20/83	EPO			
	GB 2126094 A	3/21/84	Great Britain			
	84/01298	4/12/84	PCT			
	1107854	8/15/84	Soviet Union			
	1124960	11/23/84	Soviet Union			
	60-31706	2/18/85	Japan			No
	60-43984	3/8/85	Japan			No
Lit. 1	283078	5/1/85	Spain			No
	0 162 005	11/21/85	EPO			
	1217374	3/15/86	Soviet Union			
	GB 2164277 A	3/19/86	Great Britain			
	1222254	4/7/86	Soviet Union			
	0 179 695	4/30/86	France			